K062278
p1/3

510(k) Premarket Notification
Spacelabs Medical
Clinical Event Interface (CEI), Model 91847
Summary of Safety and Effectiveness

SEP 19 2006

Classification Information:	System, Network and Communication, Physiological Monitors Specialty Cardiovascular Product Code MSX Regulation 21CFR §870.2300 Class II
Common/Usual Name:	Remote Alarm Notification System
Proprietary Name:	Spacelabs Medical Clinical Event Interface (CEI), Model 91847
Est. Registration Number:	3023361
Performance Standard:	No special controls have been identified for this product under 21CFR §870.2300

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

Subject:	510(k) Summary of Safety and Effectiveness Information for the Spacelabs Medical Clinical Event Interface (CEI), Model 91847
Submitter:	Spacelabs Medical, Inc. PO Box 7018 Issaquah, WA 98029 David J. Geraghty Phone: 1 425 657 7200 Fax: 1 425 657 7207 david.geraghty@slmd.com
Proprietary Name:	Spacelabs Medical Clinical Event Interface (CEI), Model 91847
Common Name and Classification:	Remote Alarm Notification System (Cardiovascular, Product Code MSX, 21CFR §870.2300, Class II)

Device Description:

The Spacelabs Medical Clinical Event Interface (CEI), model 91847, is a software module intended to be installed on an Off-The-Shelf (OTS) computer system utilizing a Microsoft operating system. The primary purpose of the CEI is to forward patient monitor alarm event information, originating from a Spacelabs Patient Monitoring network, to a messaging and notification system for delivery to the healthcare provider via wireless pagers. The system is also capable of providing vital signs updates at regular intervals. CEI allows nurses to be aware of their patients' alarm conditions when they are away from the patient and the monitoring system.

CEI is an open design utilizing an OTS messaging system that is compatible with the Motorola CP1250 paging systems. The Clinical Event Interface includes a software module, created by Spacelabs Medical, that accesses patient data acquired from a Spacelabs Medical Patient Monitoring System. The monitoring system forwards the data to a database. The Spacelabs Medical software module recognizes when new information has become available. It accesses and formats that data for delivery to the Emergin Integrated Messaging System, an OTS software package. The Emergin software accepts input from the Spacelabs program, reformats it and passes it on to the paging encoder, an OTS component of the system. The paging encoder formats the data for the Motorola CP1250 pager and forwards it to the pager base station for transmission to the pager. The Spacelabs Medical CEI provides a complete, end-to-end solution for paging and incorporates all of these components in a single offering.

The CEI messaging system provides for the sending patient information in a text only or text and graphic format to the Motorola CP1250 pager. The CEI system is designed to forward alarm information as the alarms are recognized by the patient monitoring network. The system is also cable of being set up to periodically forward a patient's physiological data at predetermined intervals.

The Spacelabs Medical ICS Clinical Event Interface (CEI), model 91847, system is a secondary alarm notification system. It does not replace the primary alarm function of the bedside monitor.

Intended Use:

The intended use of the Spacelabs Medical Clinical Event Interface is to interface with the Spacelabs monitoring network in order to provide a secondary means of annunciating and displaying patient alarm information to mobile healthcare providers. The device is indicated for use in real-time monitoring of routine patient status and alarm events. The pager is intended to serve as a parallel, redundant mechanism to inform the clinical staff of patient events The Waveform Pager System is intended for use as a secondary alarm in any hospital environment currently using or intending to use a Spacelabs patient monitoring network The Clinical Event Interface supplements the primary patient-monitoring system by providing a forwarding mechanism for annunciating and displaying patient alarm events and the critical information associated with the events - including parameter values and waveforms, typically within 4 - 8 seconds of an alarm event on the patient monitor The pager provides an audio or vibrating alert along with a series of displays showing patient identification, alarm parameters, and up to a 12-second waveform snapshot.

The Spacelabs Medical Clinical Event Interface is a secondary alarm. It does not replace the primary alarm function on the monitor.

Test Discussion:

The Spacelabs Medical Clinical Event Interface (CEI), Model 91847 and the Spacelabs Medical Clinical Messenger, model 91841, K992749 are substantially equivalent in design concepts, technologies and materials. CEI was validated through rigorous testing that, in part, support the compliance of the CEI software module and its OTS components to the Standards mentioned in Section 6 of this submission. Additionally, the CEI software was developed following a robust software development process and was fully specified and validated. The test program included all of the components of the system and verified that as data became available to CEI it was acquired and forwarded through to the pager.

Test Conclusion:

The Spacelabs Medical Clinical Event Interface (CEI), Model 91847, is substantially equivalent to its predicate devices in design concepts, technologies and materials. Testing demonstrates that CEI is as safe and effective as Spacelabs Medical Clinical Messenger, model 91841, K992749.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2006

Spacelabs Medical Inc.
c/o Mr. David J. Geraghty
Manager, Regulatory and Quality
5150 220th Ave SE
PO Box 7018
Issaquah, WA 98027-7018

Re: K062278
Trade Name: Spacelabs Medical Clinical Event Interface (CEI), Model 91847
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm).
Regulatory Class: Class II (two)
Product Code: MSX
Dated: August 22, 2006
Received: August 24, 2006

Dear Mr. Geraghty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062278

Indications for Use

510(k) Number (if known): _____

Device Name: **Spacelabs Medical Clinical Event Interface (CEI), Model 91847**

Indications for Use:

The intended use of the Spacelabs Medical Clinical Event Interface is to interface with the Spacelabs monitoring network in order to provide a secondary means of annunciating and displaying patient alarm information to mobile healthcare providers. The device is indicated for use in real-time monitoring of routine patient status and alarm events. The pager is intended to serve as a parallel, redundant mechanism to inform the clinical staff of patient events. The Clinical Event Interface System is intended for use as a secondary alarm in any hospital environment currently using or intending to use a Spacelabs patient monitoring network. The Clinical Event Interface supplements the primary patient-monitoring system by providing a forwarding mechanism for annunciating and displaying patient alarm events and the critical information associated with the events - including parameter values and waveforms, typically within 4 - 8 seconds of an alarm event on the patient monitor. The pager provides an audio or vibrating alert along with a series of displays showing patient identification, alarm parameters, and up to a 12-second waveform snapshot.

The Spacelabs Medical Clinical Event Interface is a secondary alarm. It does not replace the primary alarm function on the monitor.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062278